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REMARKS

The Amendments

Claims 11 and 23 are amended to render moot the 35 U.S.C. § 112 rejection, as discussed below. Claims 7, 17 and 28 are amended to be consistent with the language of claim 1.

It is submitted that the above amendments would put the application in condition for allowance or materially reduce or simplify the issues for appeal by clearly removing a ground of rejection. The amendments do not raise new issues or present new matter and do not present additional claims. The amendments have been made to address the newly made 35 U.S.C. § 112 rejection and thus was not earlier presented. Accordingly, it is submitted that the requested amendments should be entered.

To the extent that the amendments avoid the prior art or for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Restriction Requirement

Applicants maintain their traversal of the restriction requirement. It is respectfully urged that separate classification and search, alone, is not sufficient basis for restriction. Applicants refuted the previously alleged basis for the restriction and no new proper basis has been alleged. The claimed compositions, methods and kits are obviously closely related.

The compositions and kits contain the same ingredients and are both useful in the claimed method. It is urged that the restriction be withdrawn.

The Rejection under 35 U.S.C. § 112, First Paragraph

The rejection of claims 11-14, 16, 18-22 and 33 is believed to be rendered moot by the amendment to claim 11. As stated in the Office Action, deleting the term prevent in claim 11, which has been done, overcomes the rejection. The term is also deleted from withdrawn claim 23.

The First Rejection under 35 U.S.C. § 103

The rejection of claims 1-4, 6, 10-14, 16, 20-22, 33 and 34 under 35 U.S.C. § 103, as being obvious over Miller (U.S. Patent No. 6,174,513) in view of Bannerjee (US Pub. 2002/0151598) is respectfully traversed.

Miller teaches compositions and methods for stabilizing radiolabeled peptides and proteins contained in a diagnostic or therapeutic radiopharmaceutical composition by use of surfactants alone or surfactants in combination with salts. Miller teaches that the radiolabeled peptides or proteins contain a radionuclide and a carrier agent designed to target a specific organ or tissue site in the body, with the radionuclide optionally being affixed to the carrier. See, e.g., col. 1, lines 15-23 and 46-54. The optional salts disclosed for use by Miller are the chloride salts listed at col. 5, lines 42-43.

As stated in the Office Action, Miller lacks any teaching of including in its compositions or kits a compound which provides or generates iodide ions.

Bannerjee teaches compositions and methods for treating symptoms of bronchoconstrictive disorders, such as asthma. The compositions contain a bronchodilating

agent, such as described in paragraphs [0008] - [0010] of the publication. The compositions are provided in a stabilized solution form which gives them long shelf life, i.e., in terms of 1-3 years. See, e.g., paragraph [0006]. Bannerjee teaches as an optional embodiment of its invention that tonicity adjusting agents may be added to its compositions, paragraph [0056]. Of the about 70 particular examples of various types of such agents are include potassium iodide and sodium iodide. These are the only two iodide agents mentioned.

The apparent basis for the rejection is that it would have been obvious to one of ordinary skill in the art, in view of Bannerjee, to adjust the tonicity of the compositions of Miller and that it would have been obvious to select potassium iodide or sodium iodide from the 70 listed by Bannerjee to do so and that by making such a modification to Miller it would inherently result that the iodide ions would stabilize the radionuclides in the Miller compositions. Applicants respectfully disagree.

In order to establish obviousness under 35 U.S.C. § 103, the mere fact that the prior art could be modified or two prior art references combined to arrive at the claimed invention is insufficient. The prior art must suggest to one of ordinary skill in the art the desirability of the necessary modification or combination. See In re Laskowski, 10 USPQ2d 1397 (Fed. Cir. 1989); and, In re Geiger, 2 USPQ2d 1276 (Fed. Cir. 1987). There is no desirability provided by the reference, i.e., no motivation, for one of ordinary skill in the art to adjust the tonicity of the Miller compositions by applying the method of Bannerjee. First, there is no teaching in Miller to suggest that there is any need or desire to adjust the tonicity of the Miller compositions. There is also no teaching in Miller which would lead one of ordinary skill in the art to believe that a tonicity adjusting agent would not, in fact, be harmful to the objectives of the Miller invention. Further, there is no suggestion from Bannerjee or from Miller to suggest that a means for adjusting tonicity in a composition for effecting

bronchodilating activity would be desired or even useful in a composition, such as Miller's, containing a radiopharmaceutical. The compositions of Bannerjee and Miller are completely unrelated in terms of constituents, activities and applications. One of ordinary skill in the art would not have a reasonable expectation that a tonicity adjusting teaching for one type of composition would work – and would not be detrimental – in a completely different composition.

The Bannerjee and Miller references are so unrelated that they represent non-analogous art and one of ordinary skill in the art would not have even considered Bannerjee to provide teachings for modifying the Miller compositions. The criteria for determining whether prior art is analogous, and thus potentially combinable, are: (1) whether the prior art is in the same field of endeavor, and (2) if the prior art is not in the same field of endeavor, whether a reference is reasonably pertinent to a particular problem with which the other reference is involved. See, In re Deminski, 230 USPQ 313 (Fed. Cir. 1986); and, In re Clay, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992). Neither of these criteria are met here for the reasons stated above.

For all of the above reasons, it is urged that one of ordinary skill in the art would not have been motivated to combine the Miller and Bannerjee references in the manner suggested in the Office Action. For at least this reason, the rejection under 35 U.S.C. § 103 should be withdrawn.

Additionally, it is submitted that, even if one of ordinary skill in the art would have combined Miller and Bannerjee, the claimed invention would still not be suggested. Even if there was a desire to use the tonicity adjusting embodiments of Bannerjee, there is no suggestion to one of ordinary skill in the art to select the particular iodide salts from Bannerjee as the tonicity adjusting agents. Since the two iodide salts are only a small portion

of the tonicity adjusting agents taught by Bannerjee, one would not necessarily achieve the advantage of stabilizing the radionuclide by following the tonicity adjustment teachings of Bannerjee. One would have to, without any direction to do so, pick one of the two iodide salts from the 70 listed compounds. Further, Bannerjee indicates that sodium chloride is preferred, not iodide. Because the advantage in radionuclide stabilization would only be achieved on the off chance the iodide salt is selected, it is not an inherent result of the combination. An argument for obviousness based on inherency of a modification of the reference is only permissible if the element alleged to be inherent is suggested from the prior art. Otherwise, this is merely an impermissible use of hindsight. See, In re Rijckaert, 28 USPQ2d 1955 (Fed. Cir. 1993), wherein the CAFC stated that:

“ ‘That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.’ In re Spormann, 150 USPQ 449, 452 (CCPA 1966). Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. See In re Newell, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989).”

The only teaching or suggestion to modify Miller to add a tonicity adjusting agent of Bannerjee and to select one of the two iodide salts from the 70 compounds Bannerjee recites comes by hindsight reconstruction of applicants' own teachings. Such is not an adequate substitute for actual teachings in the prior art motivating the combination of the reference teaching and the selection of a specific remotely mentioned embodiment thereof. Such hindsight reconstruction does not support obviousness under 35 U.S.C. § 103.

For this additional reason, the rejection under 35 U.S.C. § 103 should be withdrawn.

The Second Rejection under 35 U.S.C. § 103

The rejection of claims 8-9, 18-19 and 32 under 35 U.S.C. § 103, as being obvious over Miller in view of Bannerjee further in view of Blum is respectfully traversed.


Blum, like Miller, teaches nothing about combining iodide ions with a radiopharmaceutical. For reasons analogous to those discussed above, it would not have been obvious to one of ordinary skill in the art to modify the Blum compositions in view of Bannerjee to provide such iodide ions. Even if Miller were modified to use the depreotide agent of Blum, there would be no suggestion to apply the teaching of Bannerjee to such a composition, nor any other teachings suggesting applicants' invention.

Accordingly, this rejection under 35 U.S.C. § 103 should also be withdrawn.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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